

REMARKS

The Office Action dated August 29, 2007, has been received and carefully considered. In this response claims 1-4, 6-14, 16-21 have been amended, and claim 22 has been cancelled without prejudice. No new matter has been added. Entry of the amendments to the claims 1-4, 6-14, 16-21, and 23-25, and the cancellation of claim 22 without prejudice are respectfully requested. Reconsideration of the outstanding rejections in the present application is also respectfully requested based on the following remarks.

At the outset, the undersigned thanks the Examiner for the courtesies extended during the interview conducted on September 27, 2007.

I. THE NON-STATUTORY SUBJECT MATTER REJECTION OF CLAIMS 1-18 AND 25

On page 9 of the Office Action, claims 1-18 and 25 were rejected under 35 USC § 101 as being directed to non-statutory subject matter. This rejection is hereby respectfully traversed.

Applying the State Street test for patentable subject matter, the Examiner asserts that claims 1-9 and 11-17 fail to set forth that the operation of the claimed elements are

tangibly embodied on an article of manufacture. Applicants respectfully disagree.

First of all, Applicants respectfully submit that amended claims 1-18 and 25 listed above, are directed to statutory subject matter and withdraw of the non-statutory subject matter rejection is respectfully requested.

Second, claims 1-9 and 11-17 do not recite anything regarding a mathematical algorithm, but rather recite a useful process under 35 U.S.C. 101. Indeed, amended independent claims 1, 11 and 25 recite methods for collecting and reporting outcomes data for benchmarking ambulatory surgical procedures. These methods recite steps that lead to the useful, concrete, and tangible result of "generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm." The amended independent claims 1 and 11, further recites "collecting outcomes data sets associated with a medical procedure for a plurality of individuals" as recited in claim 1 or "collecting primary source surgical outcomes data sets including a plurality of responses to a set of indicators for a plurality of patients," as recited in claim 11, which further establish the useful, concrete and tangible result of the present application. Additionally, these methods do not recite mathematical algorithms, as the Examiner implies. Indeed, the claimed steps of collecting, converting,

establishing, and generating are clearly not part of a mathematical algorithm.

Third, the Examiner has misunderstood and misapplied the legal test for patentable subject matter as formulated by the Federal Circuit in State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368 (Fed. Cir. 1998). Specifically, there is no requirement that a system or process must claim elements tangibly embodied on an article of manufacture in order to qualify as patentable subject matter.

Since the famous phrase of "a useful, concrete and tangible result" has been misquoted and misunderstood too often, Applicants have reproduced below the section of the State Street opinion where the court discussed the "Mathematical Algorithm" exception.

The Supreme Court has identified three categories of subject matter that are unpatentable, namely "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185, 101 S.Ct. 1048. Of particular relevance to this case, the Court has held that mathematical algorithms are not patentable subject matter to the extent that they are merely abstract ideas. [citations omitted.] In *Diehr*, the Court explained that certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application, i.e., "a useful, concrete and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557.

Unpatentable mathematical algorithms are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not "useful." From a practical standpoint, this means that to be patentable an algorithm must be applied in a "useful" way. In *Alappat*, we held that data, transformed by a machine through a series of mathematical calculations to produce a smooth waveform display on a rasterizer monitor, constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it produced "a useful, concrete and tangible result"-the smooth waveform.

Similarly, in *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053, 22 USPQ2d 1033 (Fed.Cir.1992), we held that the transformation of electrocardiograph signals from a patient's heartbeat by a machine through a series of mathematical calculations constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it corresponded to a useful, concrete or tangible thing-the condition of a patient's heart.

Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete and tangible result" - a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

State Street, 149 F.3d at 1373 (Emphasis added). From reading the above-quoted passages, it may be appreciated that the phrase

"a useful, concrete and tangible result" is nothing more than an expression of the well-known utility requirement -- namely, a claimed invention as a whole must accomplish a practical application.

In the first passage quoted above, the court indicates that "some type of practical application" of an abstract idea is required for an invention to qualify as patentable subject matter.

In the Alappat case, as discussed in the second passage quoted above, the court found "data, transformed by a machine through a series of mathematical calculations to produce a smooth waveform display on a rasterizer monitor" to constitute a practical application of an abstract idea. Although the waveform was eventually displayed on a rasterizer monitor, it was the useful data transformation itself, not the final display, that qualified the invention as a practical application.

This is confirmed by the court's discussion of the Arrhythmia case, as cited in the third passage quoted above, where no reference is made as to whether or how the transformed electrocardiograph signals were output or displayed. Rather, the court rests its conclusion solely on the fact that the transformation of electrocardiograph signals "corresponded to a

useful, concrete or tangible thing - the condition of a patient's heart."

In the fourth passage quoted above, the court holds that "the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation." This conclusion was based on the observation that "a final share price momentarily fixed for recording and reporting purposes" constituted "a useful, concrete and tangible result." Again, the court does not condition the conclusion on any output or display of the transformed data (i.e., the final share price).

As explained above, the phrase "a useful, concrete and tangible result" is but a short-hand expression for the utility requirement. It simply means that an abstract idea, by itself, is not useful and therefore not entitled to patent protection. In requiring claiming elements that are tangibly embodied on an article of manufacture, the Examiner has apparently put improper emphasis on the word "tangible." However, according to MPEP § 2106 at IV.C.2(1)(b), the tangible requirement only requires that the claim must recite more than a 35 U.S.C. § 101 judicial exception, in that a process claim must set forth a practical application of that judicial exception to produce a real-world

result. Clearly, the present claims recite more than a judicial exception, as well as a practical application of that judicial exception to produce a real-world result (i.e., generating at least one outcomes monitoring report). Thus, nothing more is needed for these claims and their respective dependent claims to qualify as statutory subject matter.

Regarding claims 10, 18, and 25, in addition to the foregoing arguments, Applicants direct the Examiner to the case law set forth in In re Beauregard, 35 USPQ 2d 1383, 1384 (Fed. Cir. 1995), In re Lundgren, (B.P.A.I. Case No. 2003-2088 (September 28, 2005)), and others, which clearly provide a patentable subject matter basis for these claims. In view of the agreement reached during the Examiner Interview, Applicants previously amended claims 10, 18, and 25 to remove any doubt regarding patentable subject matter. That is, claims 10, 18, and 25 were amended to recite at least one processor readable carrier for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the steps of collecting, converting, establishing, and generating, which are clearly not part of a mathematical algorithm and are clearly directed to practical applications that produce a useful, concrete and tangible result.

In the "Response to Arguments" section, the Examiner alleges that claims 10, 18 and 25 do not fall within any of the four statutory classes because processor readable carrier signal is embodied a carrier wave. Applicants believe that the Examiner has failed to understand the present invention as recited in these claims. It is respectfully submitted that processor readable carrier is an element and not a signal embodied a carrier wave. Nowhere in the claims 10, 18 and 25 does the Applicants claim a signal or wave as alleged by the Examiner. However, in order to further prosecution, Applicants have amended "processor readable carrier" in claims 10, 18 and 25 to "computer readable medium."

If the Examiner does not fully understand the claimed invention, Applicants would be more than willing to work with the Examiner to provide further clarification. If the Examiner does understand the claimed invention fully, Applicants respectfully request a more concrete explanation of the legal and factual bases for the aforementioned nonstatutory subject matter rejection. The Examiner has presented very little, if any, analysis to explain why the claimed invention is not directed to statutory subject matter. According to MPEP § 2106 section IV.B, "the burden is on the USPTO to set forth a *prima facie* case of unpatentability. Therefore, if USPTO personnel determine that it is more likely than not that the claimed



subject matter falls outside all of the statutory categories, they must provide an explanation." The Examiner has not met this burden of proof.

In view of the foregoing, it is respectfully requested that the aforementioned non-statutory subject matter rejection of claims 1-18 and 25 be withdrawn.

## II. THE ANTICIPATION REJECTION OF CLAIMS 1-25

On page 10 of the Office Action, claims 1-25 were rejected under 35 U.S.C. § 102(e) as being anticipated by Menzie et al. (U.S. Patent No. 6,650,932). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 102, the Patent Office bears the burden of presenting at least a prima facie case of anticipation. In re Sun, 31 USPQ2d 1451, 1453 (Fed. Cir. 1993) (unpublished). Anticipation requires that a prior art reference disclose, either expressly or under the principles of inherency, each and every element of the claimed invention. Id.. "In addition, the prior art reference must be enabling." Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). That is, the prior art reference must sufficiently describe the claimed invention so as to have placed the public in possession of it. In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed.

Cir. 1985)). "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." Id.

The Examiner asserts that Menzie et al. discloses the claimed invention. However, Menzie et al. issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie et al. has an effective filing date of May 15, 2000.

Applicants again respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Applicants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Applicants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Applicants have done) in a declaration, but actual dates of

diligence must be provided (which Applicants have provided) (see MPEP 715.07).

In view of the foregoing, Applicants respectfully submit that Menzie et al. is not a proper prior art reference for application against the claims of the present application.

Moreover, regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that Menzie et al. discloses the claimed invention. However, it is respectfully submitted that Menzie et al. fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedure comprising the steps of: "collecting outcomes data sets associated with a medical procedure for a plurality of individuals," as presently claimed. Menzie et al. relates to an individual patient's clinical condition, and a technical device for directly viewing the physiological patient data. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Menzie et al. fails to disclose, or even suggest, "collecting outcomes data sets associated with a medical procedure for a plurality of individuals (e.g., patients)," as recited in independent claims 1, 11, 19, 24 and 25. Rather, Menzie et al. discloses multiple

collection devices 132a-n connected to two processing center 140 and 142. The Examiner merely alleges that the "system is able to collect numerous patients/individuals information." However, no support can be found for such allegation in Menzie et al. Furthermore, Menzie et al. discloses a single patient and a single visit or a single clinical episode captured via a single display screen. In contrast, the present application captures multiple patient visits displayed on multiple display screens. Also, Menzie et al. fails to disclose or even suggest "a medical procedure," as recited in independent claims 1, 11, 19, 24 and 25. Menzie et al. merely discloses that heart rate variability monitors perform signal analysis on physiological signals, and fails to disclose "a medical procedure."

It is also respectfully submitted that Menzie et al. fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedure comprising the steps of: "establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the outcomes data sets," as recited in independent claims 1, 11, 19, 24 and 25. Instead, Menzie et al. merely discloses a value of 40 mmHg and fails to disclose or even suggest that the 40 mmHg value is established "based at least in part on an outcomes data group." Also, Menzie et al. does not disclose, or even suggest, calculations

or comparisons with other patients, but rather only with one patient. Further, Menzie et al. does not disclose, or even suggest, calculations or comparisons with other medical procedures, but rather only that heart rate variability monitors perform signal analysis on physiological signals. Further, Menzie et al. does not disclose, or even suggest, calculations or comparisons with other organizations, but rather only with one organization at a time. Indeed, Menzie et al. does not disclose, or even suggest, a medical benchmarking system in any manner. In contrast, the present application discloses making benchmark (comparison) calculations across multiple patients for multiple medical procedures for the purpose of comparing multiple organizations. The present application claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator), across any organization (e.g., ambulatory surgery center).

In view of the foregoing, it is respectfully submitted that Menzie et al. fails to disclose, or even suggest, the claimed invention as set forth in claims 1, 11, 19, 24, and 25. Accordingly, it is respectfully submitted that claims 1, 11, 19, 24, and 25 should be allowable over Menzie et al.

Regarding claims 2-10, 12-18, and 20-23, these claims are dependent upon independent claims 1, 11 and 19. Thus, since

independent claims 1, 11 and 19 should be allowable as discussed above, claims 2-10, 12-18, and 20-23 should also be allowable at least by virtue of their dependency on independent claims 1, 11 and 19. Moreover, these claims recite additional features which are not disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned anticipation rejection of claims 1-25 be withdrawn.

IV. THE OBVIOUSNESS REJECTION OF CLAIMS 1-3, 5-13, 15-19 AND 21-25

On page 14 of the Office Action, claims 1-3, 5-13, 15-19 and 21-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kraf et al. (U.S. Patent No. 5,299,119) in view of Seare et al. (U.S. Patent No. 6,223,164). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The Patent Office can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of references. Id..

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). That is, under 35 U.S.C. § 103, teachings of references can be combined only if there is some suggestion or motivation to do so. Id. However, the motivation cannot come from the applicant's invention itself. In re Oetiker, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). Rather, there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the art would make the combination. Id.

Kraft et al. fails to teach or suggest a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedures. Instead, Kraf et al. discloses a device for performing automated calculations for a single patient over time for determining normal or abnormal heart rate variation. Kraf et al. does not disclose, or even suggest, calculations or comparisons with other patients, but rather only with one patient. Also, Kraf et al. does not disclose, or even suggest, calculations or comparisons with other medical procedures, but rather only with one medical procedure. Further, Kraf et al. does not disclose, or even suggest, calculations or comparisons with other organizations, but rather

only with one organization at a time. Indeed, Kraf et al. does not disclose, or even suggest, a medical benchmarking system in any manner. In contrast, the present application discloses making benchmark (comparison) calculations across multiple patients for multiple medical procedures for the purpose of comparing multiple organizations. The present application claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator), across any organization (e.g., ambulatory surgery center).

The Examiner acknowledges that Kraf et al. fails to disclose the claimed feature of "collecting data from a plurality of individuals," recited in independent claims 1, 11, 19, 24 and 25, but asserts that Seare et al. discloses this claimed feature and thus the claimed invention would have been obvious in view of the combination of Kraf et al. and Seare et al. However, Seare et al. is not an analogous art, and thus teaches away from Kraft et al. Specifically, Seare et al. discloses a mechanism for assessing medical service utilization patterns or a mechanism for converting raw medical providers billing data into an information historical database. See column 4, lines 28-36. Kraft et al. on the other hand, discloses a device for performing automated calculations for a single patient over time for determining normal or abnormal



heart rate variation. Thus, Seare et al. is not an analogous art to Kraft et al. and one having ordinary skill in the art would not combine a mechanism for converting billing data into an information historical database with a device for determining normal or abnormal heart rate variation of Kraft et al.

Also, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-3, 5-13, 15-19 and 21-25 be withdrawn.

V. THE OBVIOUSNESS REJECTION OF CLAIMS 1-25

On page 18 of the Office Action, claims 1-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brown (U.S. Patent No. 6,101,478) in view of Seare et al. (U.S. Patent No. 6,223,164). This rejection is hereby respectfully traversed.

Regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that Brown substantially discloses the claimed invention. However, it is respectfully submitted that Brown fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking ambulatory surgical procedures comprising the steps of: "collecting outcomes data sets for a plurality of patients," as recited in claims 1, 11, 19, 24 and 25. Instead, Brown discloses "a system for remotely identifying and monitoring a plurality of individuals." See column 3, lines 19-21. In particular, Brown discloses the network system for remotely identifying and monitoring an individual at a time. Thus, Brown fails to disclose or even suggest "collecting outcomes data sets associated with a medical procedure," as recited in claim 1 or "collecting primary source surgical outcomes data sets including a plurality of responses to a set of indicators for a plurality of patients," as recited in claim 11.

Furthermore, Applicants respectfully submit that Brown fails to disclose or even suggest "establishing a norm based at least in part on an outcomes data groups, the outcomes data group comprising a plurality of the outcomes data set associated with the medical procedure," as recited in claims 1, 11, 19, 24 and 25. The Examiner merely alleges that the norm is the mediums indicated on the graph in Figure 10. However, Brown

fails to disclose or even suggest establishing a "norm based at least in part on an outcomes data groups." Furthermore, Brown discloses obtaining a single outcomes data set and not a plurality of outcomes data sets. Thus, Brown fails to disclose or even suggest "establishing a norm based at least in part on an outcomes data group, the outcome data group comprising a plurality of the outcomes data set associated with the medical procedure."

Additionally, the Examiner acknowledges that Brown fails to disclose the claimed feature of "collecting data from a plurality of individuals," recited in independent claims 1, 11, 19, 24 and 25, but asserts that Seare et al. discloses this claimed feature and thus the claimed invention would have been obvious in view of the combination of Brown and Seare et al. However, Seare et al. is not an analogous art, and thus teaches away from Brown. Specifically, Seare et al. discloses a mechanism for assessing medical service utilization patterns or a mechanism for converting raw medical providers billing data into an information historical database. See column 4, lines 28-36. Brown, on the other hand, discloses a system used to collect data relating to the health status of the patients. The data can be used by healthcare providers or pharmaceutical companies for research or marketing purposes. See column 5, lines 56-60. Thus, Seare et al. is not an analogous art to

Brown and one having ordinary skill in the art would not combine a mechanism for converting billing data into an information historical database with a system for collecting data relating to the health status of the patients of Brown.

Also, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-25 be withdrawn.

#### VI. CONCLUSION

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the

present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

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